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10/019,714	12/28/2001	Bernhard Eistert	KEIL/149/PC/US	1040

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ALIX YALE & RISTAS LLP
750 MAIN STREET
SUITE 1400
HARTFORD, CT 06103

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/18/2003

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Office Action Summary

Application No.
10/019,714

Applicant(s)
Eistert

Examiner
Joseph Weiss

Art Unit
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 7, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Psaros (US 5765558).

In regards to claim 1, Psaros discloses a tracheal cannula (note fig 7) having a shaft (2) and a cuff (6) for blocking the tracheal cross sectional area surrounding the shaft such that a section of the shaft above the cuff has a window (44) that is covered by an air permeable membrane (46) that is fully capable and is insertable following a user undergoing a tracheotomy.

In regards to claim 2, the membrane of Psaros is made of gas permeable TEFLON, such micro-porous materials are inherently liquid water impermeable. (See e.g. US 5177996, see also TESS Reg. # 1111147)(col. 4 lines 40-45)

In regards to claim 3, Psaros discloses the membrane consisting essentially of PTFE.(col. 4 lines 40-45)

In regards to claim 4, Psaros discloses the membrane comprising PTFE.(col. 4 lines 40-45).

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros.

In regards to claims 5 & 6, Psaros substantially discloses the claimed invention except for the use of "laced" or woven PTFE as the membrane material, a.k.a. Goretex.

It is noted that applicant's specification does not set forth the use of woven PTFE, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary. See e.g. 4921642

5. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros as applied to claims 1-6 above, and further in view of Muir (US 4759356).

In regards to claims 7-12, Psaros substantially discloses the instant application's claimed invention, but does not explicitly disclose a valve that opens upon inhalation & closes upon

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exhalation at the entrance of the cannula. However, Muir disclose such (10). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Muir and used them with the device of Psaros. The suggestion/motivation for doing so would have been to permit the patient to have improved speech while tracheotomized (Note abstract & Summary of invention). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

6. Claims 13-18 & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros as applied to claims 1-6 above, and further in view of Abel (US 5056515).

In regards to claim 13-18, Psaros substantially discloses the instant application's claimed invention, but does not explicitly disclose the cuff connected via a line to a balloon means for inflation of the cuff and controlling cuff pressure. However, Abel disclose such (line 68, balloon means 70). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Abel and used them with the device of Psaros. The suggestion/motivation for doing so would have been to insure optimal

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fit of the cuff to the user's trachea without damage to the tracheal tissue. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 20, the suggested device discloses the balloon means as a pilot balloon. (See Abel 70).

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Psaros & Muir as applied to claim 7 above, and further in view of Abel (US 5056515).

In regards to claim 7, the suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the cuff connected via a line to a balloon means for inflation of the cuff and controlling cuff pressure. However, Abel disclose such (line 68, balloon means 70). The references are analogous since they are from the same field of endeavor, the respirator arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Abel and used them with the suggested device. The suggestion/motivation for doing so would have been to insure optimal fit of the cuff to the user's trachea without damage to the tracheal tissue. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

8. Applicant's arguments filed 7 Jul 03 have been fully considered but they are not persuasive.

In regards to the objection to the claims, applicant's amendment is proper & responsive and resolves the issue, hence the objection is withdrawn.

In regards to the 35 USC 112 rejections applicant's amendment is proper and responsive and resolves the issue, hence the rejections are withdrawn

In regards to the prior art rejections, applicant's amendment is proper and responsive but does not resolve the issues, hence the rejections are retained and modified as needed in response to applicant's amendments to the claims with a response to the arguments as noted below:

NOTE GENERALLY:

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111© because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of

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the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

NOTE SPECIFICALLY:

In regards to applicant's arguments on the 35 USC 102 rejection of Psaros please note Fig 7 which discloses this non-limiting preamble intended use in a structural claim limitation. Furthermore the structure of Psaros is fully capable of performing the intended use.

As for legal argumentation please note:

In response to applicant's argument that the device is intended to be used following the medical procedure of a tracheostomy, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's arguments, the recitation insertion following the medical procedure of a tracheostomy has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or

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structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In regards to the issue of permeable, poor permeability is still permeability, hence it meets the plain language of the claim. Furthermore, NO is also a component of air and its permeability is something greater than poor. Applicant has in no way positively claimed a quantification of permeability, hence the argument is not persuasive.

Applicant's conclusion that Psaros does not have all the limitations is in error, and applicant's arguments fail to establish a reasoned basis to reach this conclusion IAW patent law, see the above recitations regarding preamble & intended use and please read the reasoned basis for the 35 USC 102 rejection as noted in the body of the rejection.

In regards to applicant's arguments from page 8-16 regarding the 35 USC 103 rejections, they are not persuasive, because they are all predicated upon applicant's improper argument to distinguish over Psaros in the 35 USC 102 rejection, hence the various 35 USC 103 rejections are proper and retained.

Furthermore:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Also not the devices are not being combined, but the teachings are being combined to suggest a device, hence applicant's speculation of non-functional device is not persuasive.

Regarding the issue of "teaching away", an unspoken supposition for applicant's argument appears to be that the window applicant is using is designed/adapted etc for use as having a primary role in ventilation of the patient, i.e. handling primary flow of respiratory gases, however, this intimation from the arguments is nowhere to be found in the claim language, and limitation of the written description cannot be read into the claims except for the statutory strictures of 35 USC 112(6) or where applicant invokes specific definitions for claim language used, none of this is done. Reading the plain language of the claims and giving the language its broadest reasonable interpretation in light of the written description, the prior art anticipates and/or renders obvious the claimed invention.

Conclusion

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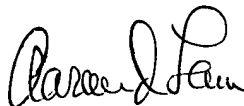
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.


J. F. Weiss

July 15, 2003


Aaron J. Lewis
Primary Examiner